

normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under § 26.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

§ 26.119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.

§ 26.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may

approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§ 26.121 [Reserved]

§ 26.122 Use of Federal funds.

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§ 26.123 Early termination of research support: Evaluation of applications and proposals.

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has have directed the scientific and technical aspects of an activity has have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

§ 26.124 Conditions.

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

PART 27—PROGRAM FRAUD CIVIL REMEDIES

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AUTHORITY: 31 U.S.C. 3809.

SOURCE: 53 FR 15182, Apr. 27, 1988, unless otherwise noted.

§ 27.1 Basis and purpose.

(a) *Basis.* This part implements the Program Fraud Civil Remedies Act of 1986, Public Law No. 99–509, sections 6101–6104, 100 Stat. 1874 (October 21, 1986), to be codified at 31 U.S.C. 3801–3812. 31 U.S.C. 3809 of the statute requires each authority head to promulgate regulations necessary to implement the provisions of the statute.

(b) *Purpose.* This part (1) establishes administrative procedures for imposing civil penalties and assessments against persons who make, submit, or present, or cause to be made, submitted, or presented, false, fictitious, or fraudulent claims or written statements to the Environmental Protection Agency, and (2) specifies the hearing and appeal rights of persons subject to allegations of liability for such penalties and assessments.

§ 27.2 Definitions

Administrative Law Judge means an administrative law judge in the Authority appointed pursuant to 5 U.S.C. 3105 or detailed to the Authority pursuant to 5 U.S.C. 3344.

Administrator means the Administrator of the United States Environmental Protection Agency.

Authority means the United States Environmental Protection Agency.

Benefit means, in the context of “statement,” anything of value, including but not limited to any advantage, preference, privilege, license, permit, favorable decision, ruling, status, or loan guarantee.

Claim means any request, demand, or submission—

(a) Made to the Authority for property, services, or money (including money representing grants, loans, insurance, or benefits);

(b) Made to a recipient of property, services, or money from the Authority or to a party to a contract with the Authority—

(1) For property or services if the United States—

(i) Provided such property or services;

(ii) Provided any portion of the funds for the purchase of such property or services; or